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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,700	01/14/2002	Colin Ratledge	401544	8613

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LEYDIG VOIT & MAYER, LTD  
700 THIRTEENTH ST. NW  
SUITE 300  
WASHINGTON, DC 20005-3960

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,700

Applicant(s)

RATLEDGE ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34,36-51,58,59,65,66, 74-82 and 83-86 is/are pending in the application.
- 4a) Of the above claim(s) 58,59,65,66 and 83-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 34,36-51 and 74-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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The amendment filed 8/23/04 is acknowledged. Claims 34, 36-51, and 74-82 are being considered on the merits.

Claims 58-59, 65-66 and 83-86 are withdrawn from consideration as directed to a non-elected invention.

The courtesy copy of references is acknowledged with thanks. However, the Information Disclosure Statement is not part of the record at this time. It is noted in this regard that the Serial No. was incorrectly directed to "10/300700".

This application contains claims 58-59, 65-66 and 83-86 drawn to an invention nonelected with traverse in Paper filed 12/29/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The amendment presented fails to comply with the **Revised Amendment Format 37 CFR 1.121**. At least Claim 40 is amended without the appropriate indication of brackets, strike-throughs and/or underlining with respect to the removal of "s" in "addition".. Correction is **required**.

For the sake of clarity and correctness, the limitation "in a medium" should be added to claim 34. In fact, the proper terminology is "in a nutrient medium" or "in a growth medium". See specification page 7, paragraph 2.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 36-51, and 74-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "comprising culturing a microorganism comprising *Cryptocodium cohnii* with a compound...". This recitation reads

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on the use of a mixed culture. This is not contemplated by the as-filed specification. As a matter of fact, each strain of *Cryptocodinium cohnii* is cultured separately in Example 1, for example.

No basis or support is found in the present specification for the use of a means to monitor pH as a “controller” to control addition of nutrients to the medium.

Therefore, this material constitutes new matter and should be deleted.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 36-51, and 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is vague indefinite and confusing in the recitation “comprising culturing a microorganism comprising *Cryptocodinium cohnii* with a compound...”. It is at least unclear what constitutes “a microorganism comprising *Cryptocodinium cohnii* See also the new matter rejection *supra*.

Claim 34 remains confusing and vague in that it is unclear how the absence of a stationary phase can be successfully determined, since all is requires for growth to stop. No clarification was provided. If continuous culturing is required, the claim should be so amended. From the as-filed specification it is apparent that a stationary phase is absent during discrete pre-culture processes and not during “culturing” for the production of DHA as claim designated.

Claim 41 is confusing because in this claim uses a means to monitor pH as a “controller” to control addition of nutrients, such as phosphorus source and vitamins to the medium. It is uncertain how this is achieved, even when reading the claim in light of the specification. See also the new matter rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 36-51, and 74-82 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Vazhappilly *et al.* taken with Kyle and Du Preez *et al.* for the reasons as stated in the last Office action and the further reasons below.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The main thrust of Applicant's argument is that the Kyle reference requires an induction period and imposition of a stationary phase for the production of DHA. However, this argument does not clearly pertain to the invention as claimed. An "induction" step cannot be considered part of the "culturing" process for the production of DHA *per se*, but rather constitutes one or more pre-culture process steps. This distinction is clearly apparent at least from Example 2 in the instant Specification wherein the cells are pre-cultured in acetic acid/acetate (Example 2, paragraph 1). The cells are adjusted to the subsequent culturing in this manner. There is no clear reference to a pre-culture step in the invention as claimed. The distinction between this pre-culture step and an induction step is not clear on this record, since DHA is not clearly synthesized in the pre-culture step.

Therefore the rejection is deemed proper and it is adhered to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

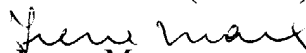
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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